K083608

ERBE USA Incorporated
Traditional 510(k): ERBE Hybrid Knife™

510(k) SUMMARY

AUG 2 6 2009

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal QA/RA Manager
Date Prepared:	February 26, 2008
Common Name:	Water Cutter/Dissector with Electrosurgical Cutting and Coagulation Capabilities
Trade/Proprietary Name:	ERBE Hybrid Knife™
Classification Name:	Jet Lavage (21 CFR Part 880.5475) and Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	FQH and GEI
Legally Marketed Predicate Device:	ERBE Monopolar Attachment for Helix Hydro-Jet 510(k) Number: K062712 and ERBE ERBEJET 2 System (Includes Applicator) 510(k) Number: K072404

Device Description:

The ERBE Hybrid Knife™ is used with the Water Jet Model ERBEJET® 2 and an ERBE ElectroSurgical Unit (ESU), VIO Model. The Water Jet delivers pressurized sterile normal saline through the Hybrid Knife to cut and dissect soft tissue. The ESU supplies High Frequency (HF) energy through a retractable electrode of the Hybrid Knife for the cutting and coagulation of tissue. The ERBE Hybrid Knife™ consists of tubing to the Water Jet, a cable to the ESU, a handle, probe tubing, and an electrode. Clinicians would assemble the device and attach it respectively to the Water Jet and ESU. For endoscopic procedures, the Hybrid Knife is placed down the channel of an endoscope that has a working channel greater than 2.8 mm. Upon the set up of the Water Jet and ESU, the Hybrid Knife is ready for use. The pedal of the ERBEJET 2 Footswitch activates its water-jet cutting capabilities. To activate cautery, the recessed electrode is extended out its tip (up to 5 mm) and the ESU's Footswitch is depressed. The ERBE Hybrid Knife™ is provided sterile and is single use.

Intended Use:

The ERBE Hybrid Knife™ is intended to be used in combination with the Water Jet System/ERBEJET 2 and an ERBE ESU VIO Model to cut and dissect soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) via the Water Jet System as well as to provide monopolar cutting and coagulation of the target tissue by the ESU in open and as well as endoscopic surgery.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBE Hybrid Knife™ has the same basic intended use as the predicate ERBE Monopolar Attachment for Helix Hydro-Jet. That is it combines water-jet cutting and dissection of soft tissue with the ability of providing cautery. It is similar to the other predicate, ERBEJET 2 Applicator, in that it works with the ERBEJET 2 Unit, functions upon the same operating principles as well as is sterilized via Ethylene Oxide, single use, and disposable. The ERBE Hybrid Knife is also manufactured by ERBE Elektromedizin GmbH.

Differences
The types of materials used for the ERBE Hybrid Knife™ are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Hybrid Knife was demonstrated. See Biocompatibility Study, III-18 to III-27. One of the other differences is that the electrode is retractable for the Hybrid Knife as opposed to being just at the end of the tip of the predicate ERBE Monopolar Attachment for Helix Hydro-Jet. Structurally and dimensionally the Hybrid Knife is different than the predicate ERBEJET 2 Applicator, in that its tip is internally different and its Outer Diameter is much smaller (2 mm versus 5 mm) with a much longer length 2200 mm versus 336 mm). The size was altered for use in 2.8 mm or larger working channels of endoscopic scopes. With a specifically designed software version of the ERBEJET 2 Unit, performance testing demonstrated the functionality of the Hybrid Knife. See Performance Testing, III-28 to III-31.

Conclusion:

The ERBE Hybrid Knife™ has the same basic intended use, principles of operation, and technological characteristics as the predicate devices in the previously cleared 510(k)s. The modifications involve having a device that connects to the Water Jet Model ERBEJET 2 and an ESU VIO Model, has a smaller outer diameter and longer working length for endoscopic use if desired, as well as retractable electrode. In conclusion, all the changes were verified or validated. As a result, the changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

ERBE USA, Inc.
% Mr. John Tartal
QA/RA Manager
2225 Northwest Parkway
Marietta, Georgia 30067

AUG 2 6 2009

Re: K083608
Trade/Device Name: ERBE USA, Inc.'s ERBE Hybrid Knife™
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH and GEI
Dated: August 19, 2009
Received: August 20, 2009

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083608

Indications for Use

510(k) Number (if known): _____

Device Name: ERBE USA, Inc.'s ERBE Hybrid Knife™

Indications For Use:

The ERBE Hybrid Knife™ is intended to be used in combination with the Water Jet System/ERBEJET 2 and an ERBE ESU VIO Model to cut and dissect soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) via the Water Jet System as well as to provide monopolar cutting and coagulation of the target tissue by the ESU in open and as well as endoscopic surgery.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

sion Sign-Off)
ion of Surgical, Orthopedic,
and Restorative Devices

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